AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

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Clinical Trials Portal

User guide for the self-assessment tool and operational metrics tool.

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Introduction

To support the delivery of high-quality clinical trial services the Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework (Governance Framework) on behalf of all jurisdictions and in collaboration with the Australian Government Department of Health. The Governance Framework provides the first step toward the accreditation of health services for the conduct of clinical trials.

The Commission has developed a web-based self-assessment tool and operational metrics tool to support the pilot and implementation of the Governance Framework.

Self-assessment tool

The self-assessment tool assists health service organisations assess their readiness to meet the actions in the Governance Framework, identify gaps and track their progress. The tool allows health service organisations to:

- Determine whether they meet the actions
- Document the evidence that demonstrates each action has been met
- Create an action plan of any tasks to meet the actions, including allocating a person responsible for completing the tasks.

Operational metrics tool

The operational metrics tool enables the workforce within trial units, clinical departments, hospitals and health networks to collect and review their clinical trial service operations through a series of automated reports. These reports may assist health service organisations with strategic planning to deliver clinical trial services. The operational report items are aligned to the National Aggregate Statistics (NAS).

About this guide

This user guide has been developed to assist with the navigation and use of the self-assessment and operational metrics tools including the registration process.

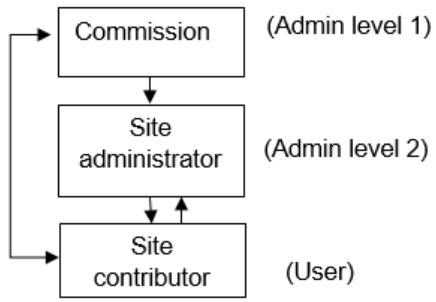
Any queries you have about this guide can be directed to the Commission Clinical Trials team via email at HMR@safetyandquality.gov.au.

How to operate the Clinical Trials portal

Registering and accessing the Clinical Trials portal

There are three types of users of the Clinical Trials portal.

Figure 1. Clinical trials portal types of users



1. Administrator level 1 - The Commission

The Commission authenticates the request for a site administrator to be registered at the health service organisation. A signed authentication from the health service organisation's CEO or delegate is required to enable this. The Commission can also authenticate the request for general users known as site contributors.

2. Administrator level 2 - Site Administrator

Once a site administrator has been registered they can:

- Complete the operational metrics and self-assessment tools
- Verify and approve general users within their own health service organisation who have registered individually (site administrators will receive a new user notification)
- Register general users within their own health service organisation.

The site administrator can assign the following level of access and visibility to general users:

Basic access	Trial unit/ clinical department access	Health service organisation access
Users are only able to access their own submissions and generate basic reports.	Users are able to access submissions from other users within the same trial units/ clinical departments and generate reports at the trial unit/ clinical department level.	Users are able to access submissions from all users within the same health service organisation and generate reports at the trial unit/ clinical department level and the health service organisation level.

The site administrator's level of access is at the health service organisation level.

3. General user – Site contributor

Site contributors can enter data and generate reports at their designated level of access:

- Basic access
- Trial unit/ clinical department access
- Health service organisation access

Contributors do not have any administrative permissions.

What email domain can be used to register

You are required to provide a health service email domain to register, either for an individual or a shared mailbox. An email address may only be used once for a single registration. Personal email domains (i.e. Hotmail or Gmail account) will not be accepted.

Accessing the Clinical Trials portal

Use the following link to access the Clinical Trials portal:
https://clinicaltrials.safetyandquality.gov.au

Registering on the Clinical Trials portal

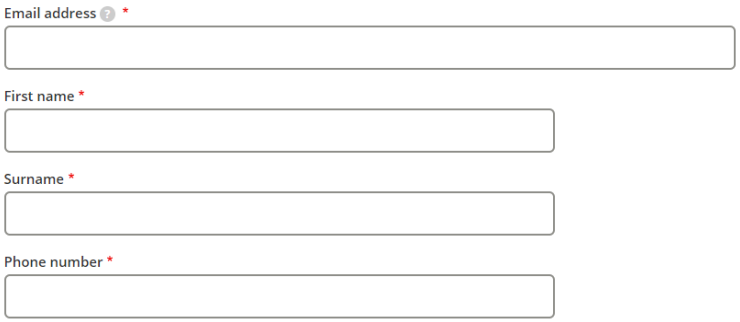
To register, select the **Register** button.

You can register either as a site contributor or as a site administrator. For more details on registering as a site administrator, see the **Registering as a site administrator** section (page 8).

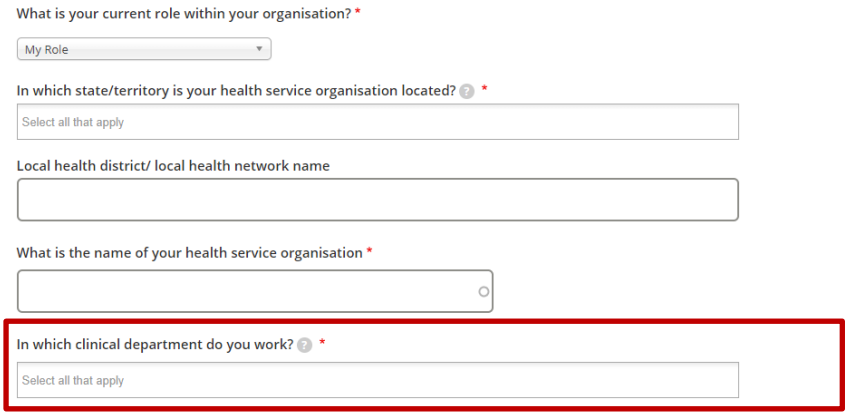
Register as a site contributor for general user access. Site contributors can enter data and generate reports. They do not have any administrative permissions.

Complete all fields to create your account.

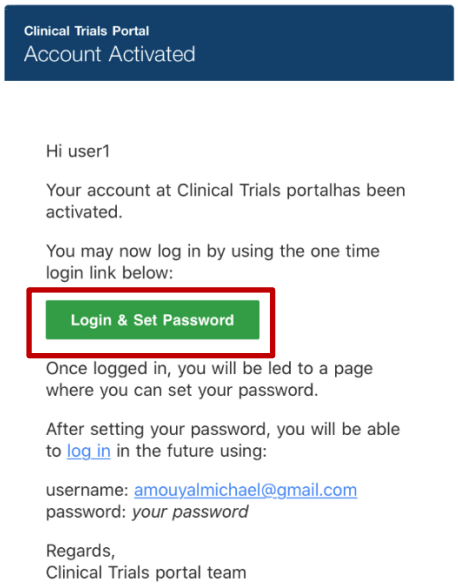
You are required to provide a professional email domain to register. That is, you cannot register using a Hotmail or Gmail account.



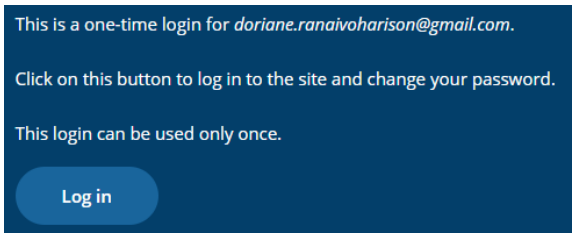
Note: We recommend that you select all the clinical departments you are involved in within your health service organisation



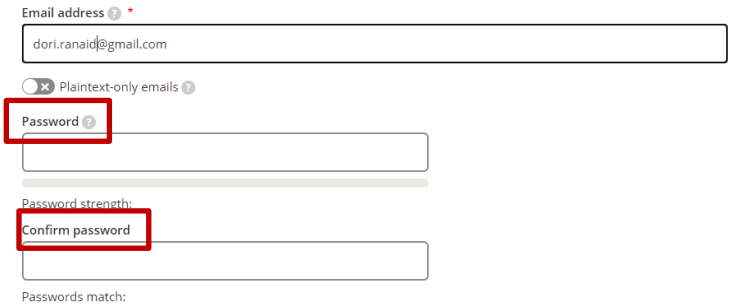
Once the registration form has been completed, your account will be verified by the site administrator. Once approved, you will receive an email containing a unique link to login and set your password.



Follow the link and log in to your account.



Once logged in, set your password. Passwords should have at least 10 characters and include uppercase and lowercase letters, numbers, and symbols.



Registering as a site administrator

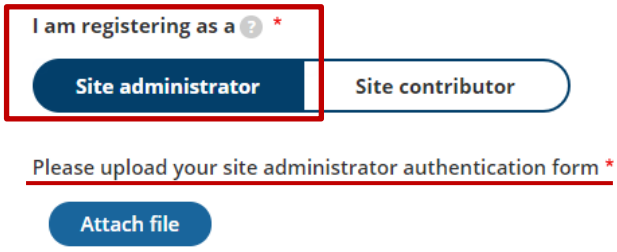
The site administrator has oversight of the clinical trials portal for his/her health service organisation. The site administrator can verify and invite general users (site contributors) for the health service organisation.

The site administrator can view all submissions from all users within his/her health service organisation for both the self-assessment and operational metrics tools.

The site administrator can provide various levels of access to site contributors:

- Basic access
- Trial unit/ clinical department access
- Health service organisation access

To register as a site administrator, you need to provide written evidence of your delegation.



The site administrator authentication form is a written document from the governing body or nominated delegate (i.e. head of department) giving you permission to administer the Clinical Trials portal within your health service organisation. This form can be a simple email or letter, stating the full name of the person(s) being nominated to act in the role of the site administrator and the name of the health service organisation. Example format below:

Dear Australian Commission on Safety and Quality in Health Care,

I am writing on behalf of [health service organisation name] to grant permission for [name of site administrator] to operate the Clinical Trials Portal.

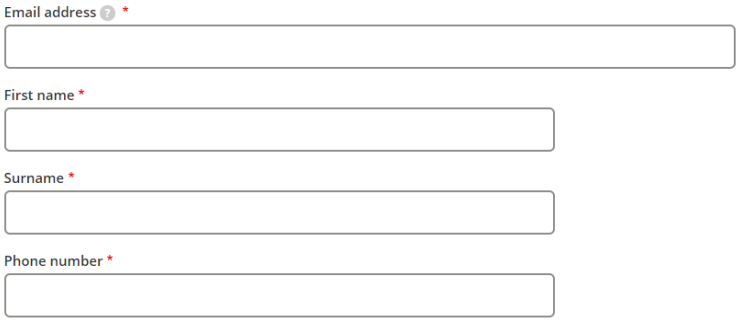
The purpose of this role will be to assist our health service organisation in monitoring our clinical trial service operations and self-assess our capacity to meet the actions within the NSQHS Standards, as provided in the Governance Framework.

Kind regards,

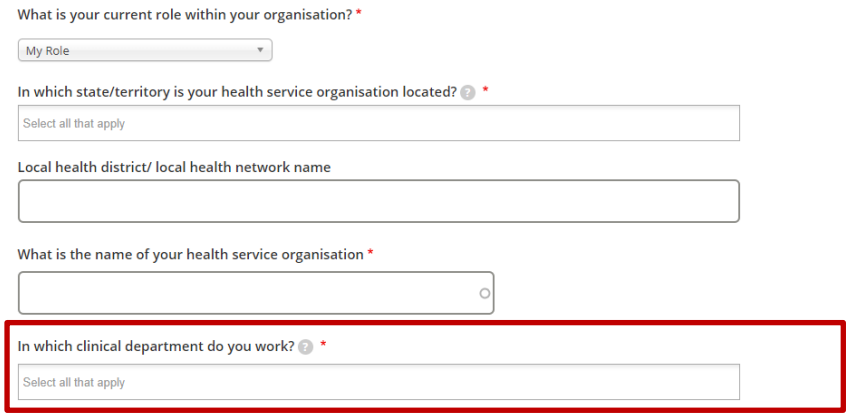
[insert signature identifying role in relationship to the health service]

Complete all fields to create your account, noting that a professional email domain is required. Enter the name of the health service organisation in full, avoiding acronyms unless relevant

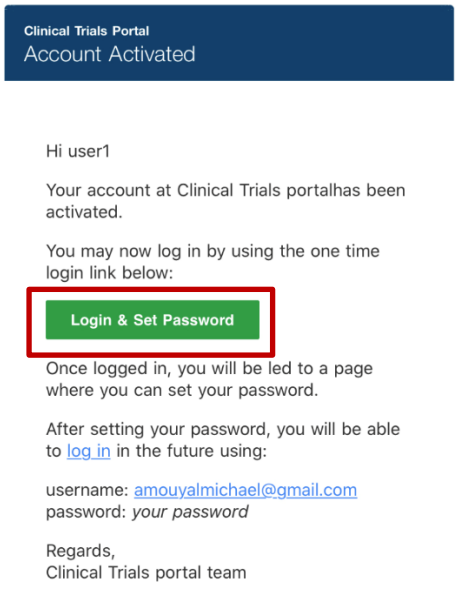
Enter a professional email domain to register.



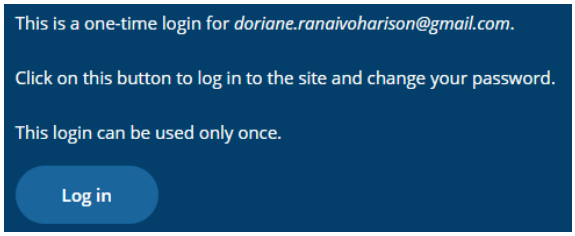
Note: When registering as a site administrator, select all the clinical departments where clinical trials are conducted within your health service organisation.



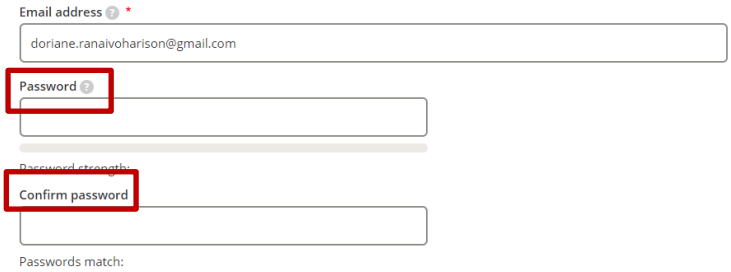
Once the registration form has been completed your account will be verified by an administrator. Once approved, you will receive an email containing a unique link to login and set your password.



Follow the link and log in to your account.



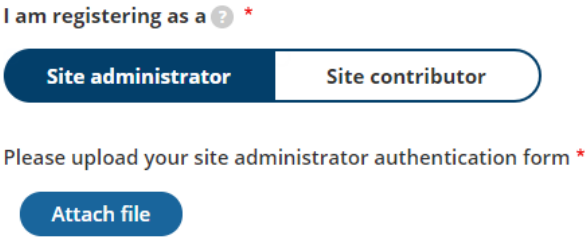
Once logged in, set your password. Passwords should have at least 10 characters and include uppercase and lowercase letters, numbers, and symbols.



Registering for several health service organisations

Site administrators are able to oversee local health districts or networks of hospitals.

To administer several health service organisations, you need to register for each individual hospital for which you have been delegated administrative rights.

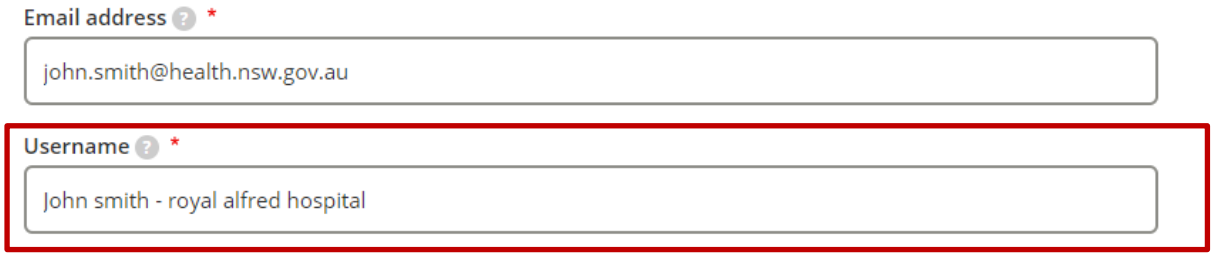


Provide your site administrator authentication for each new registration you create (you may upload the same form for all health service organisations)

Complete all fields to create your account.

Use the same email address for each health service organisation.

It is recommended that you associate the username to each hospital you administer.



Once each registration form has been completed and the accounts have been verified and approved, you will have oversight of the clinical trials portal for a network of health service organisations.

You can view all submissions from all users within the network of health service organisation for both the self-assessment and operational metrics tools.

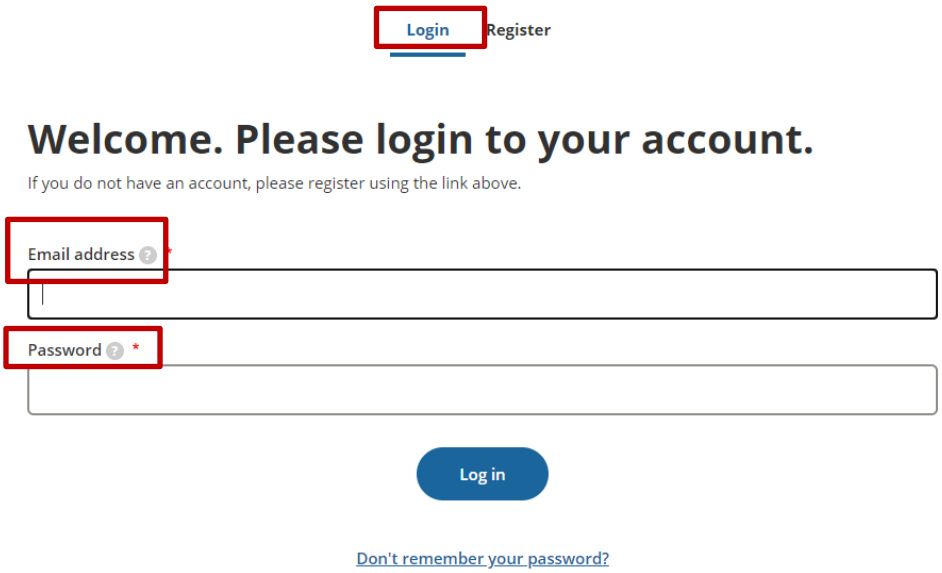
You can verify and invite general users (site contributors). You will need to login to a specific health service organisation account for which a user has registered in order to verify him/her.

Logging in to the Clinical Trials portal

To login enter your username. Your username must be a professional email address affiliated with the health service and verified by the Commission.

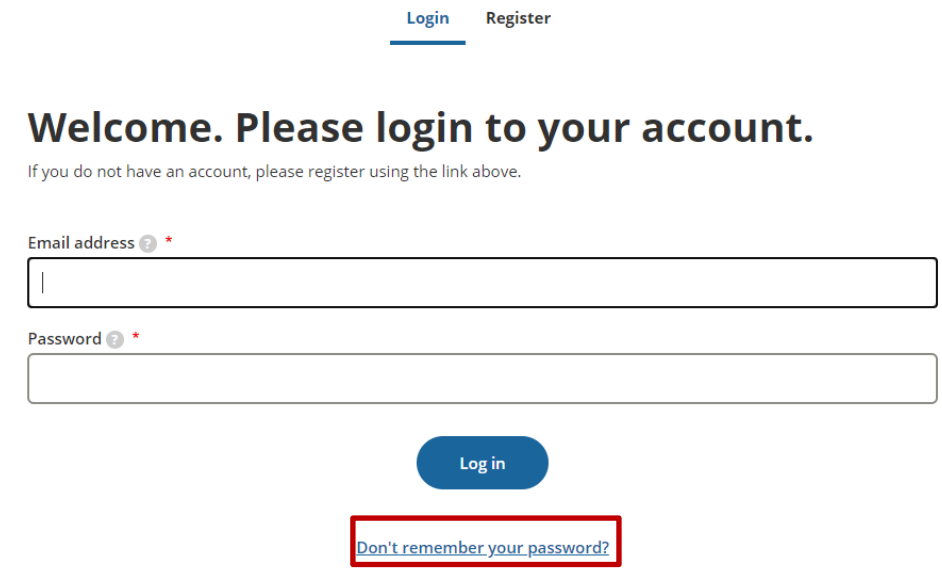
Enter your password. Passwords should have at least 10 characters and include uppercase and lowercase letters, numbers, and symbols.

If you do not have an account, you need to register using the **registration page**.

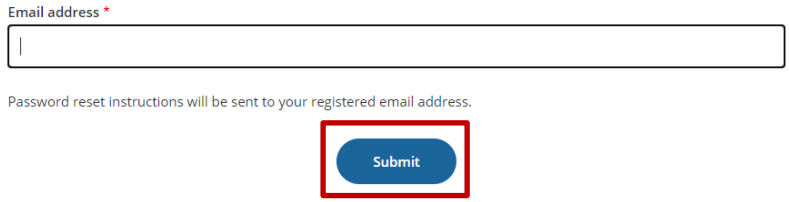


Resetting your password

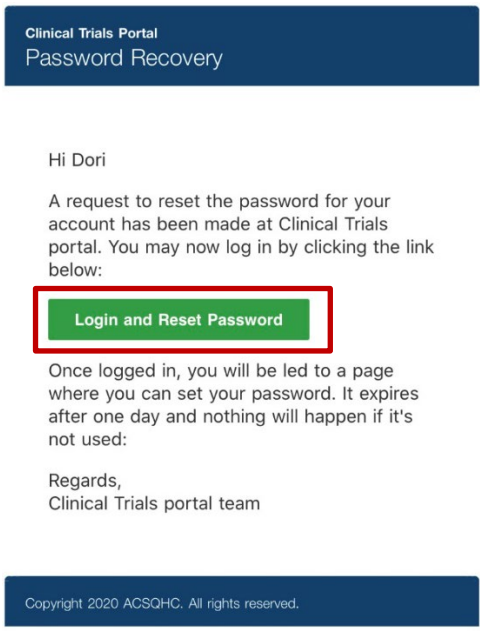
To reset your password select **Don't remember your password?**



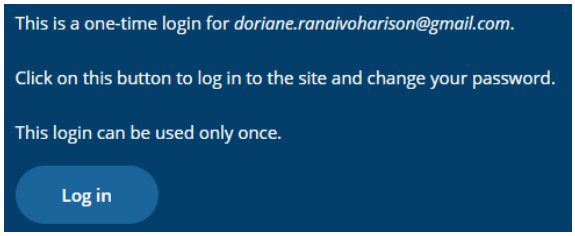
Enter your email address and select **submit.**



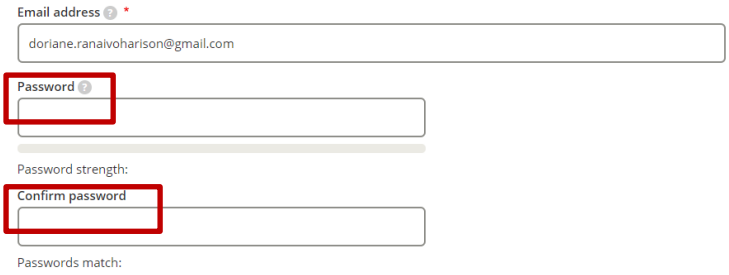
You will receive an email containing a unique link to reset your password.



Select the link and login.



Reset your password.



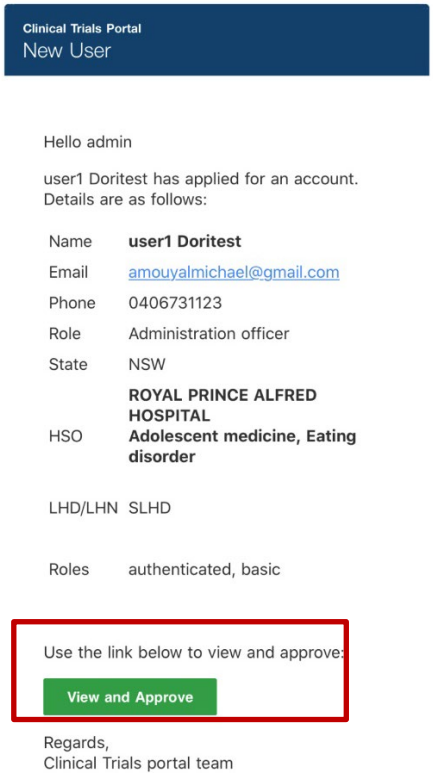
Approving and registering new users

Site administrators can approve and register/invite new users to the Clinical Trials portal.

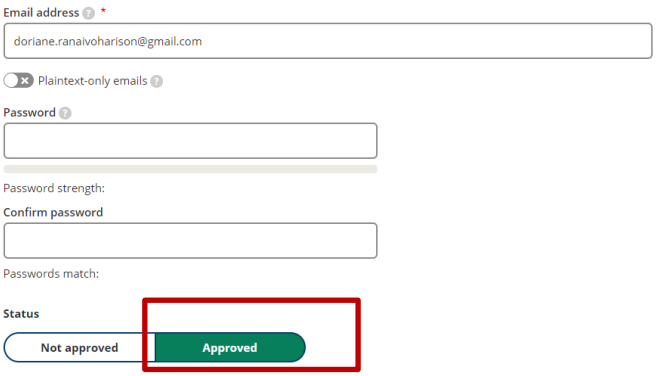
Approving new users

Once a site administrator has been identified for a health service organisation, new registrations for this health service organisation will be automatically linked to the site administrator. If you belong to a large organisation, your health service may have one or two site administrators.

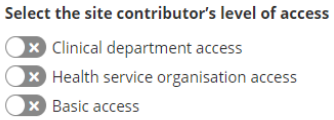
Site administrators will be notified via email of any new account that requires verification. To verify a new user, select the **View and Approve** link.



You will be taken to a page where you can review the information submitted by the user and approve his/her account.



You can assign a level of access to each user:



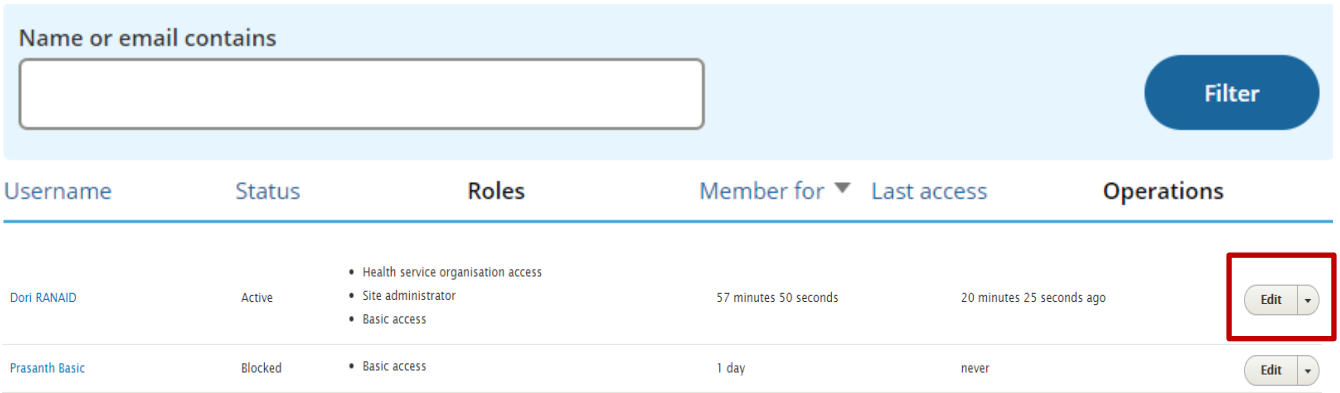
Note: The site contributor's levels of access are mutually exclusive. You should only select the highest level of access you wish to assign a user. I you select several options, they will cancel each other out.

Approving new users in the Clinical Trials portal

Site administrators can also review and approve new users directly in the Clinical Trials portal.

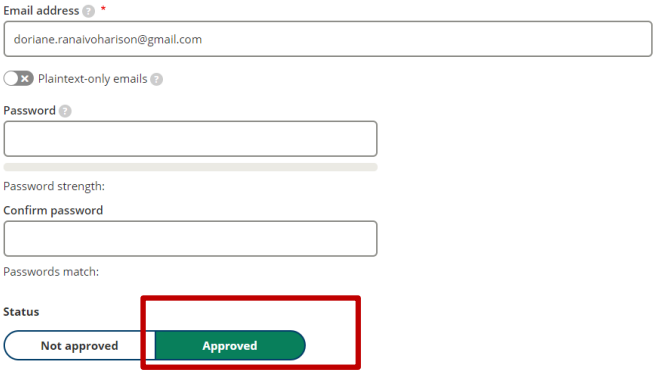
To do this, login to the portal. On the homepage, select **Approve users**.

You will be able to view the list of all users that require verification.

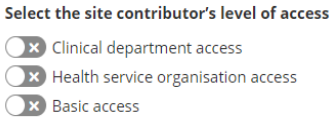


Select **Edit** to review a user.

You will be taken to a page where you can review the information submitted by the user and approve his/her account.



You can assign a level of access to each user:



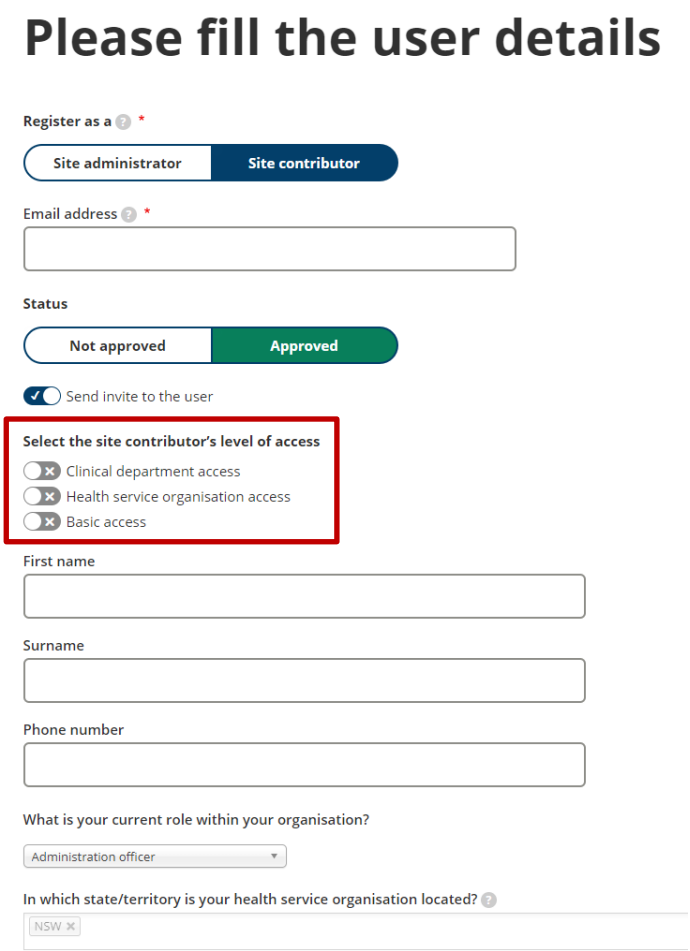
Note: The site contributor's levels of access are mutually exclusive. You should only select the highest level of access you wish to assign a user. If you select several options, they will cancel each other out and the system will default to the lowest user access level

Inviting/adding users to the Clinical Trials portal

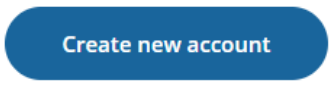
Site administrators can invite new user to join the Clinical Trials portal.

To do this, login to the portal. On the homepage, select **Add users**.

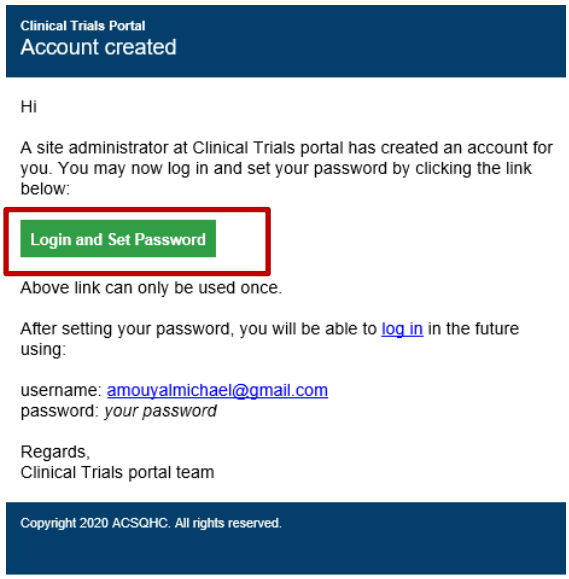
You will be taken to a page where you can fill the user's details and assign a level of access.



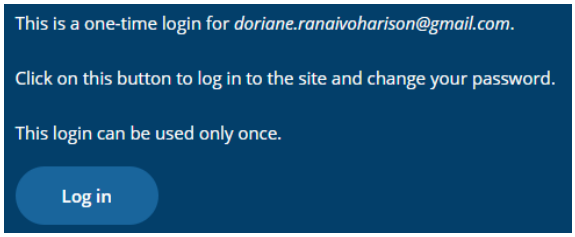
Select **Create new account**.



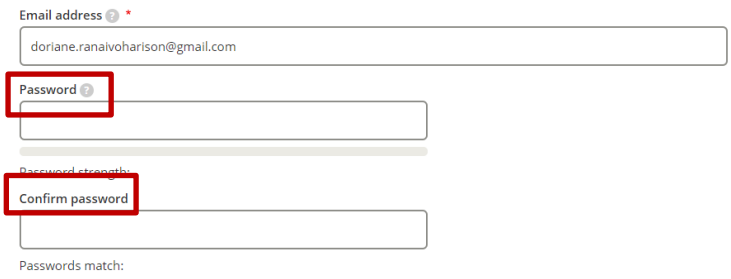
The user will be notified of his/her new account via email:



Follow the link and log in to the account.



Once logged in, set your password. Passwords should have at least 10 characters and include uppercase and lowercase letters, numbers, and symbols.

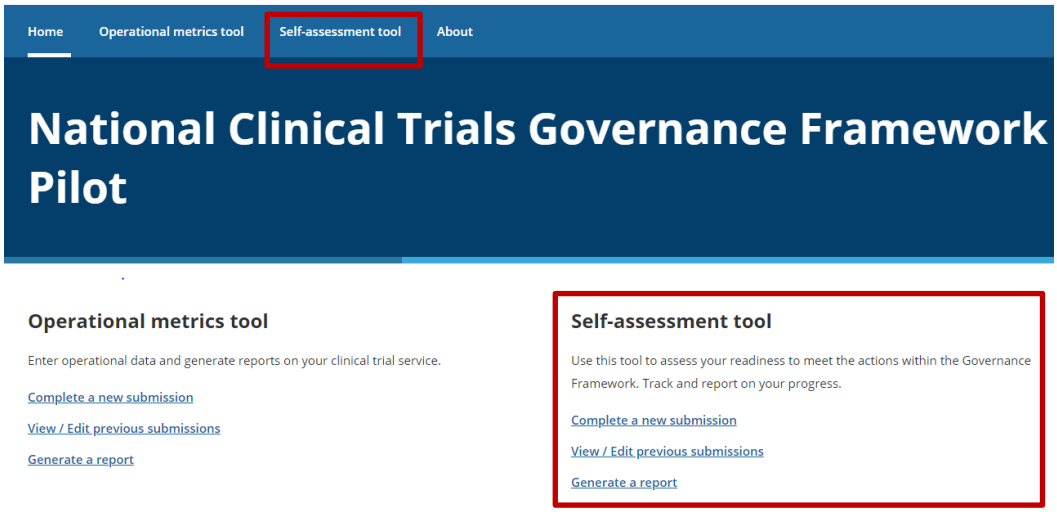


The self-assessment tool

Use the self-assessment tool to assess your health service organisation's readiness to meet the actions within the Governance Framework. Track and report on your progress.

Overview

The self-assessment tool can be accessed directly via the homepage.



The self-assessment tools allows you to:

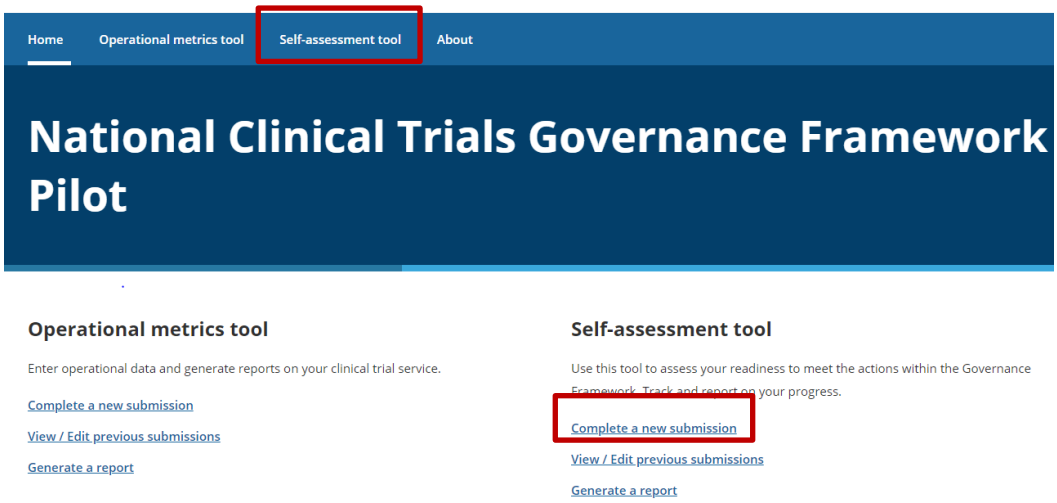
- Complete a new submission
- View / Edit previous submissions
- Generate reports.

Completing the self-assessment tool

The self-assessment tool assists health service organisations identify gaps in current systems, to plan, and track their progress in meeting the actions as provided in the Governance Framework.

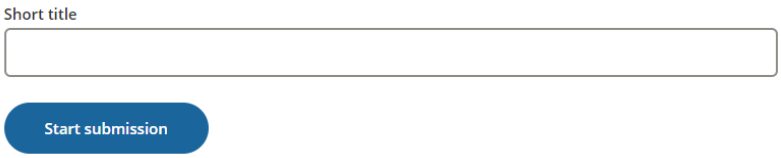
Completing a new submission

To complete a new submission, you can select **Complete a new submission** on the homepage or select **Self-assessment tool** in the upper navigation menu.

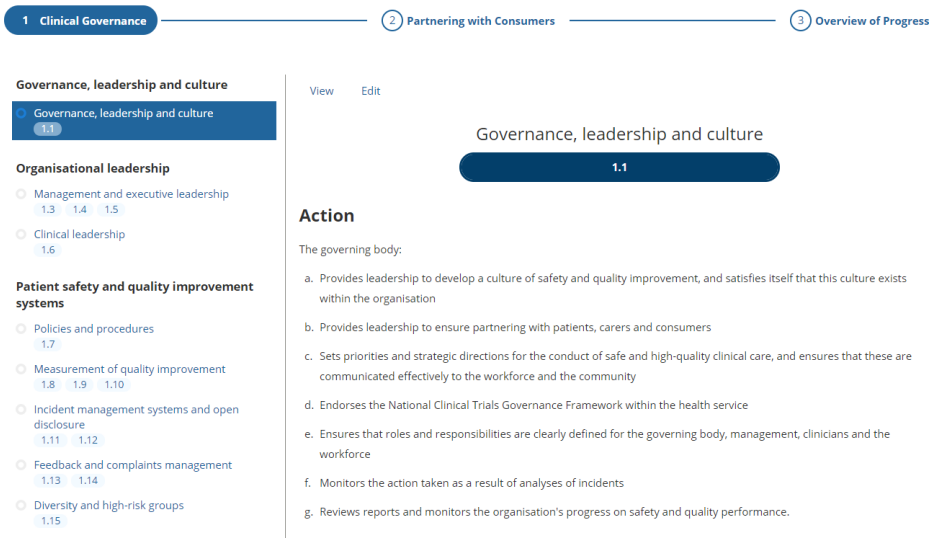


You will be asked to give a short title for each new submission. This will enable you to find existing submissions more easily.

Enter your short title and select **Start submission**.



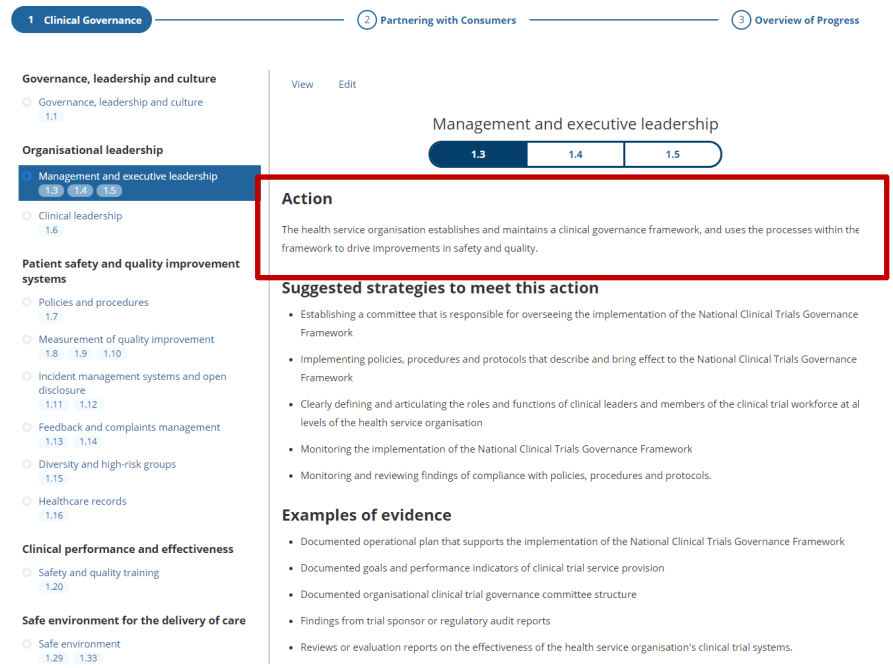
Once entered, you will be directed to the self-assessment tool.



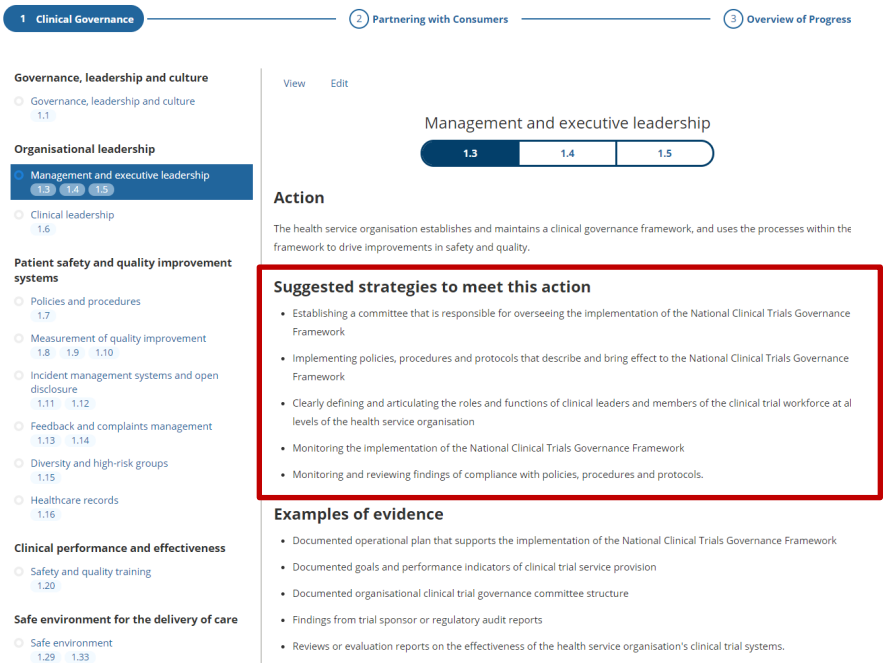
Completing an action within the self-assessment tool

The self-assessment tool includes a page for each action of the Governance Framework. Each page has the following information:

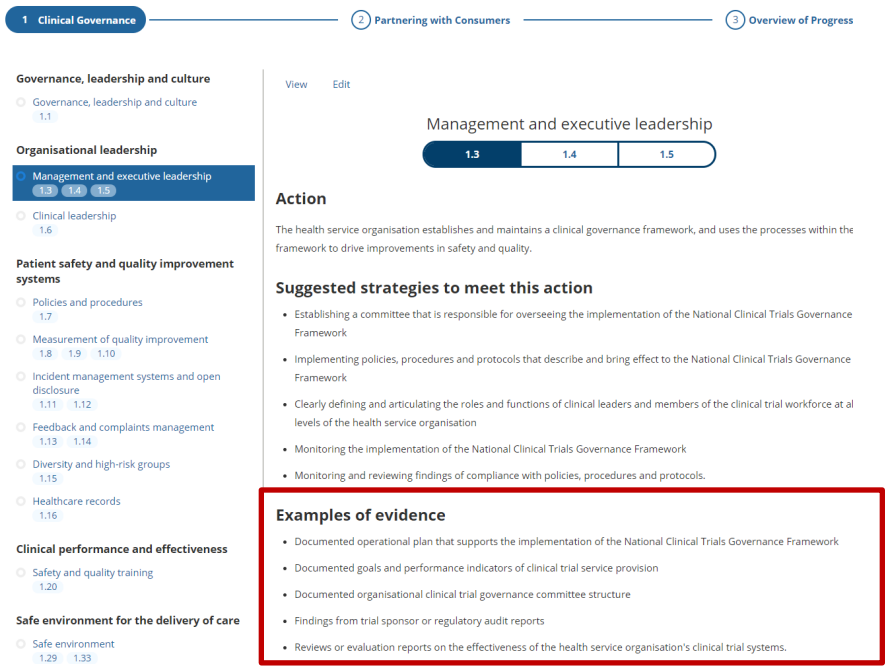
- The **actions** as provided in the Governance Framework must be met to achieve accreditation



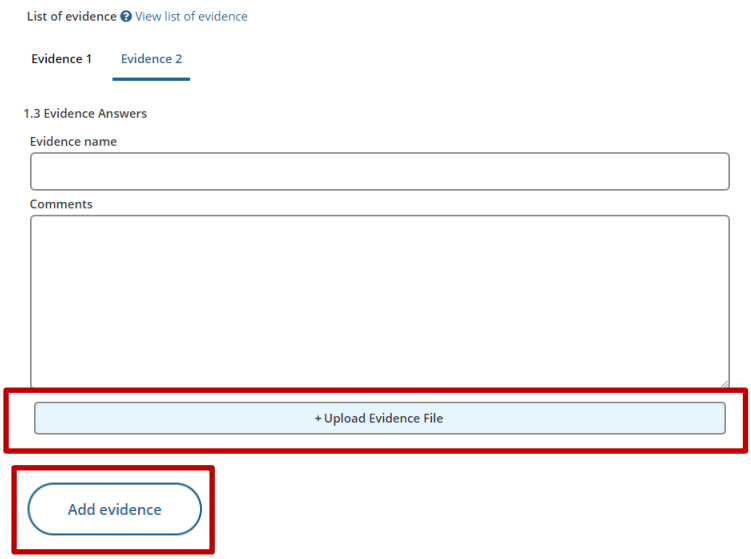
- **Suggested strategies to meet this action**. These are suggested strategies you may implement to meet the actions within the Governance Framework



- **Examples of evidence** are provided as a guide for the evidence you may provide an accreditation assessor. You may upload examples of evidence to demonstrate compliance with the action. You may provide these examples to accreditation assessors



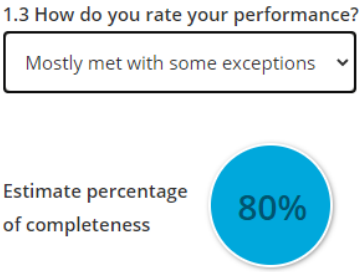
- **List of evidence** allows you to document the data or documentation that proves the action has been met. You can add several types of evidence per action. Select **Add evidence** when you want to add additional evidence. This question also allows you to upload your documents to the portal



- **How do you rate your performance?** This section requires you to estimate whether your health service organisation meets the requirement of the action

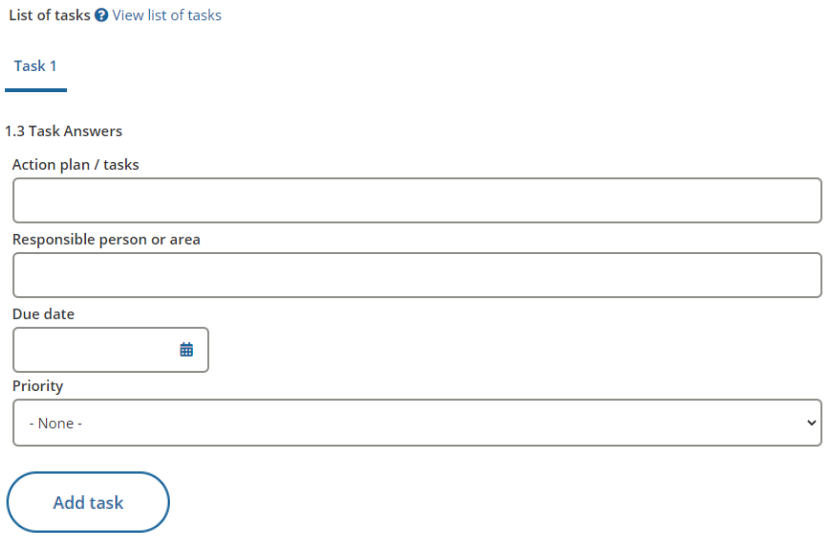
The available evidence will assist you determine the ratings. Entries are limited to:

- Met (100%)
- Mostly met with some exceptions (80%)
- Partially met (50%)
- Substantially not met (20%)



- **List of tasks** allows you to note any tasks that you may need to undertake to meet the action. It allows you to:
    - identify the person responsible for ensuring the action is met
    - adding a target date of completion for the action
    - allocating a priority rating to a task (high, medium or low).

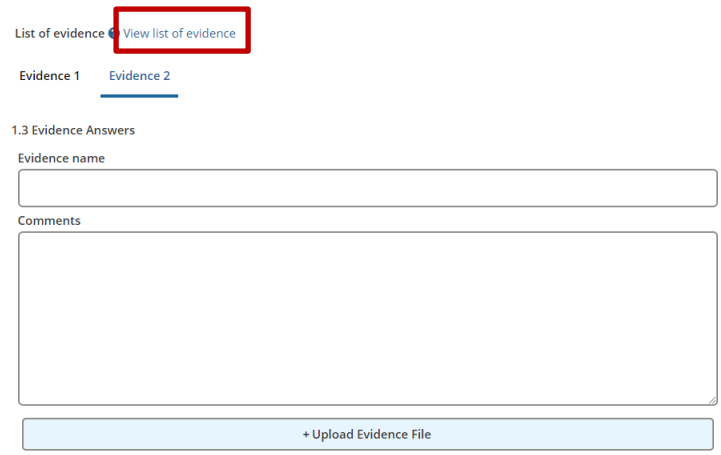
You can add several tasks per action. Select **Add task** when you want to add additional evidence.



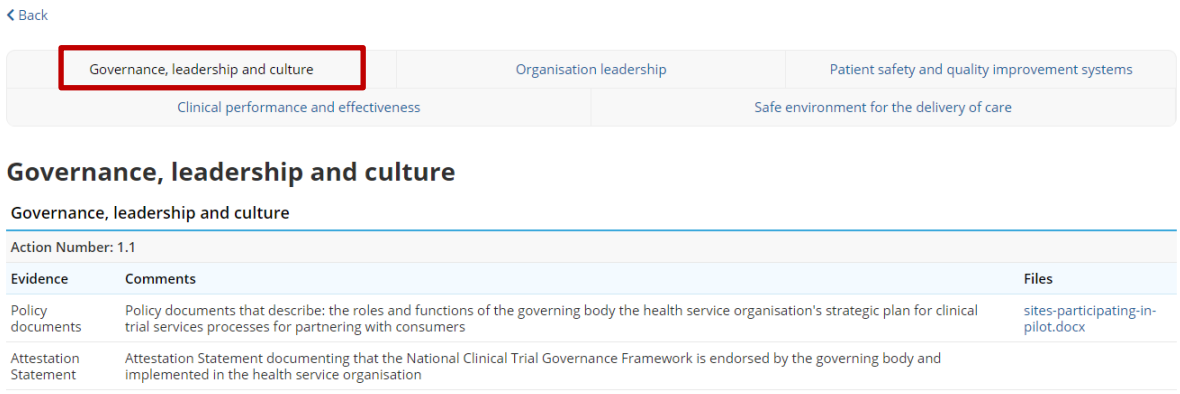
Tracking your list of evidence and the list of tasks

You can access a summary of the evidence submitted throughout the completion of the self-assessment.

Select **View list of evidence.**

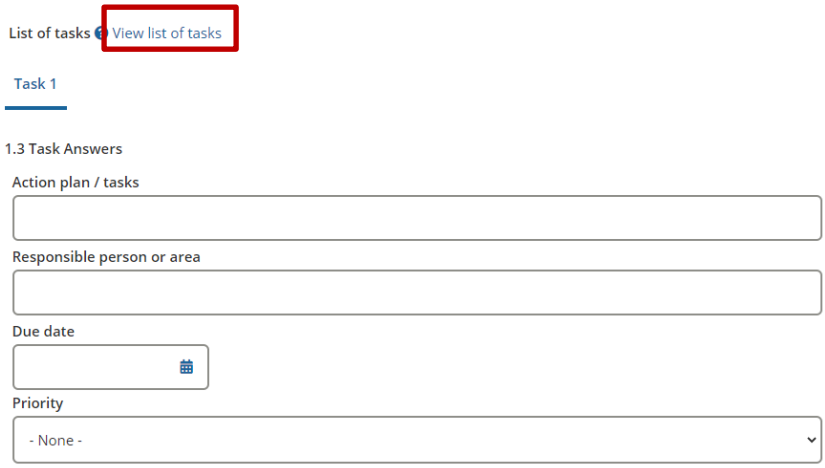


You will be directed to a page displaying the summary of your evidence and documents uploaded. Use the upper navigation menu to view the different sections of the self-assessment tool.

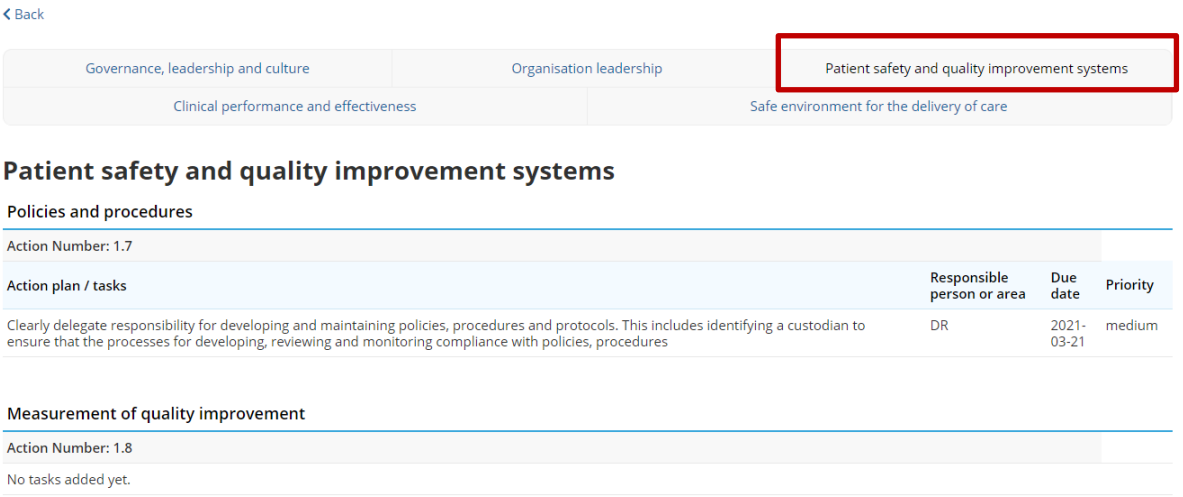


You can also access a summary of the tasks to be completed throughout the self-assessment process.

Select **View list of evidence.**



You will be directed to a page displaying the summary of tasks allocated to meet an action. Use the upper navigation menu to view the different sections of the self-assessment tool.



Navigating the self-assessment tool

You do not have to complete the self-assessment sequentially.

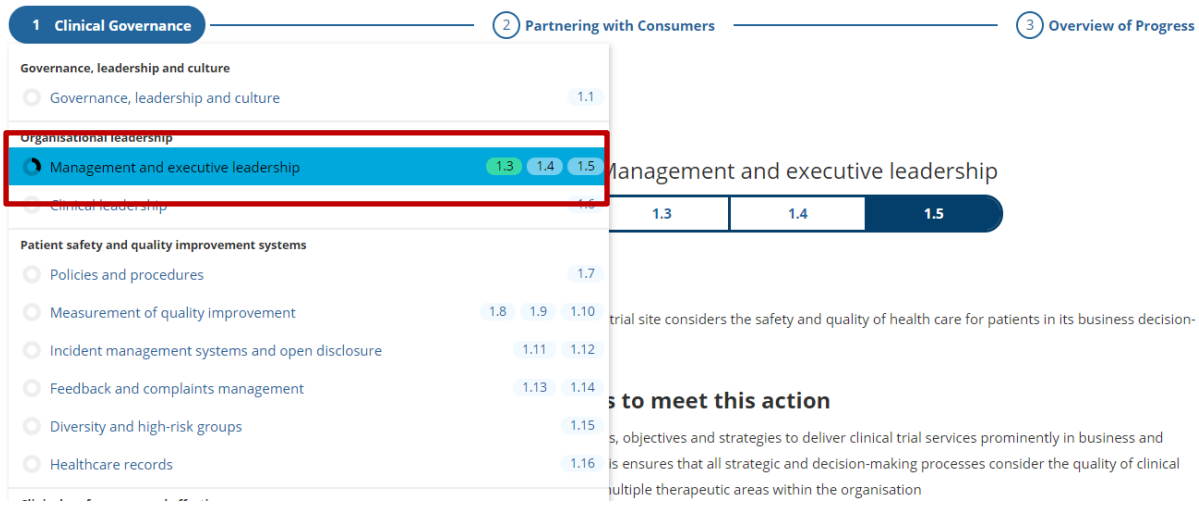
You can move between actions in no particular order.

You can also go back and forth between the Clinical Governance Standard and Partnering with Consumers Standard.

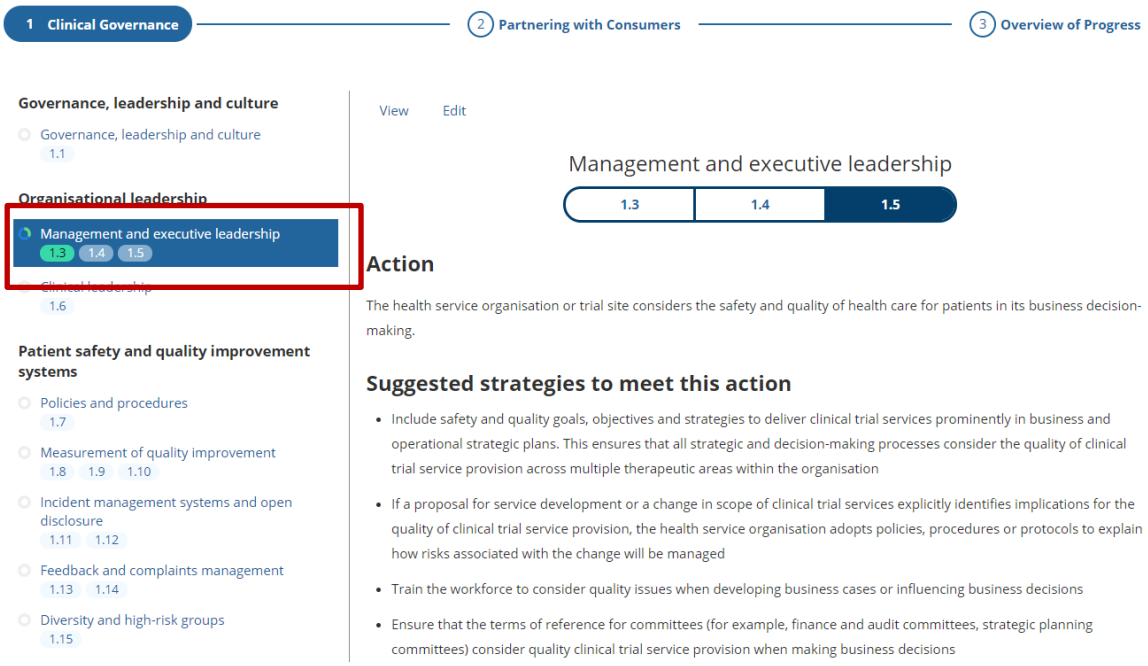
You can access and complete each action by selecting them through the upper navigation menu.

You can choose to access a subsection (e.g. select Management and executive leadership) or select a specific action (e.g. select action 1.5).

The completed actions are displayed in green (e.g. action 1.3) which allows you to track the status of completion of your self-assessment submission.



You can also select a subsection or specific action using the side navigation menu.



You can choose to complete the self-assessment progressively by selecting the **Previous** and **Next** at the end of each action's page.

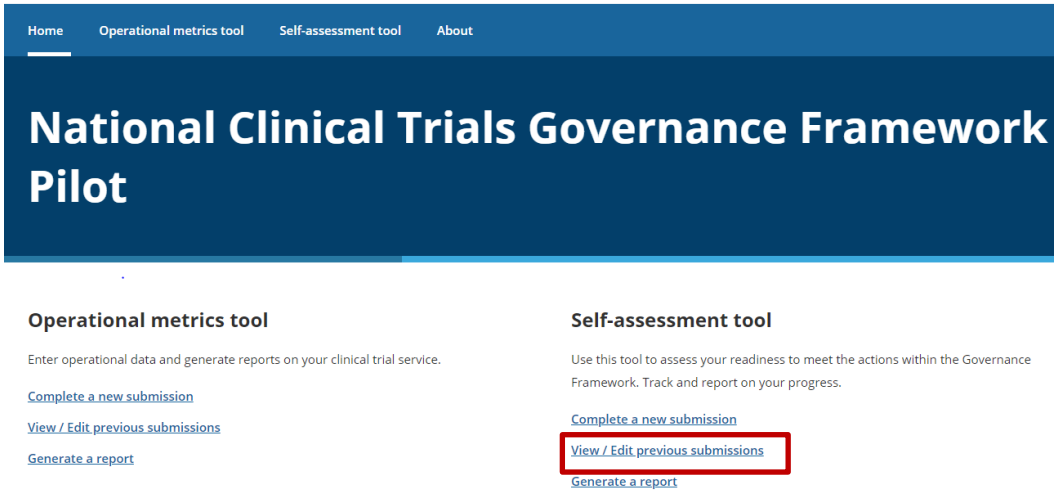
Saving drafts of the self-assessment tool

Your work is automatically saved every two minutes and when navigating between actions.

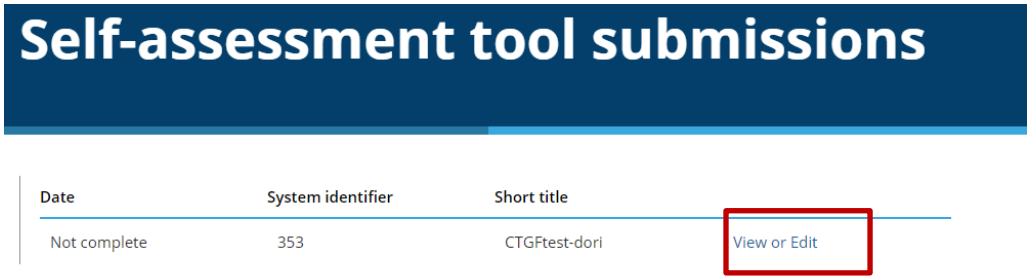
You can choose to save your work and complete it at a later date and time by selecting **Save & complete later.**

Accessing drafts or previously submitted submissions

To access draft and finalised submissions, select **View/Edit previous submissions** on the homepage.



You will be able to view the list of all previous submissions. Use the short title to identify the submission you wish to access. Select **View or Edit** to access your submission.

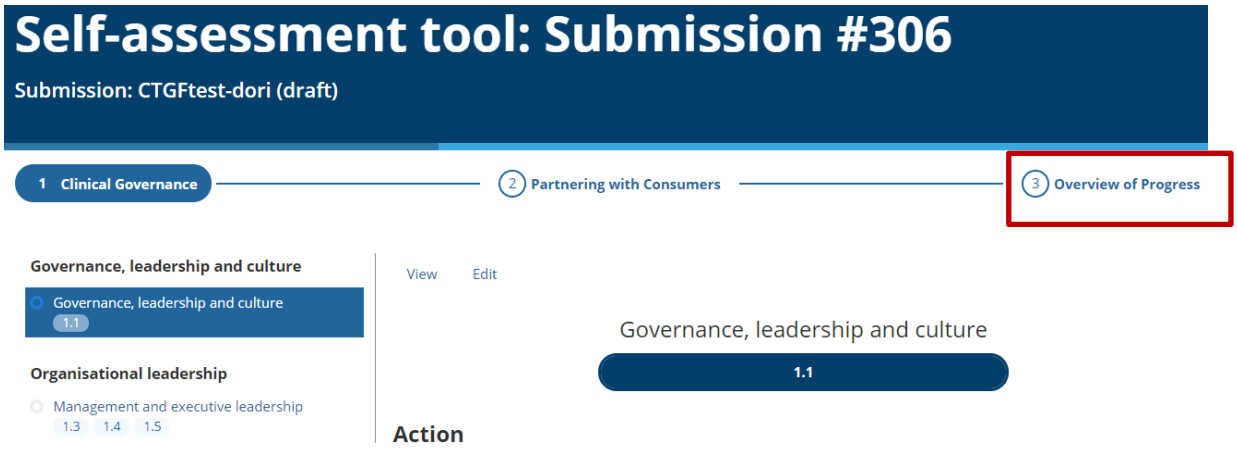


Self-assessment reports

Overview of progress

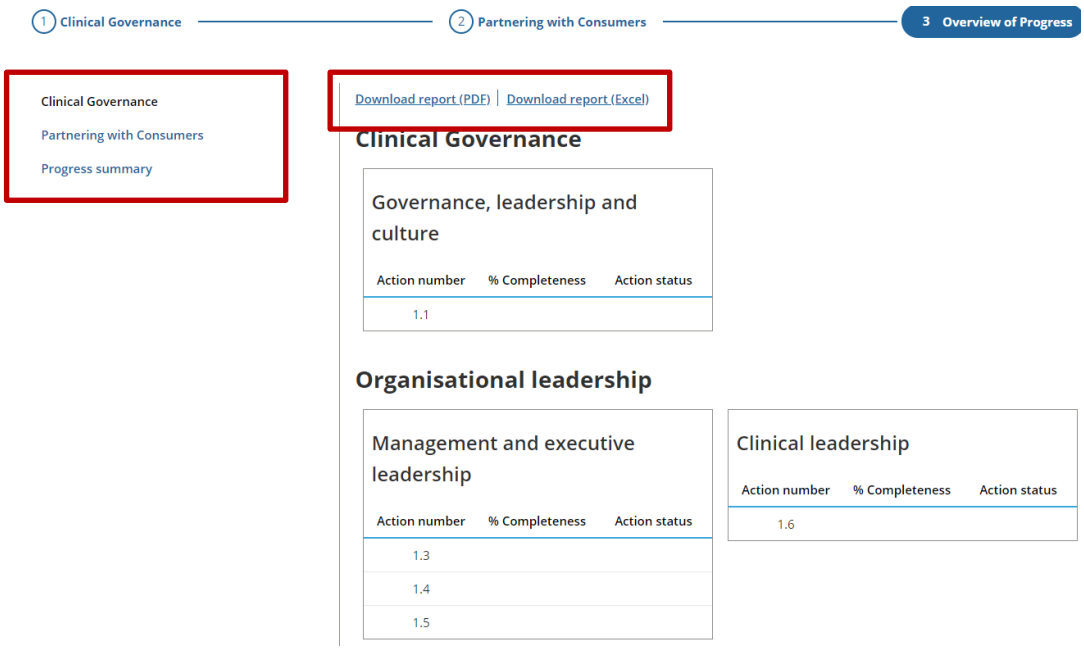
The Overview of Progress provides a summary report on the percentage completed for each action.

Select **Overview of progress** when completing/editing a submission.



You can view your health service organisation's progress online or download a PDF or Excel report.

You can access the overview of progress for the Clinical Governance Standard and the Partnering with Consumers Standards



You can also view a progress summary for all actions according to their status:

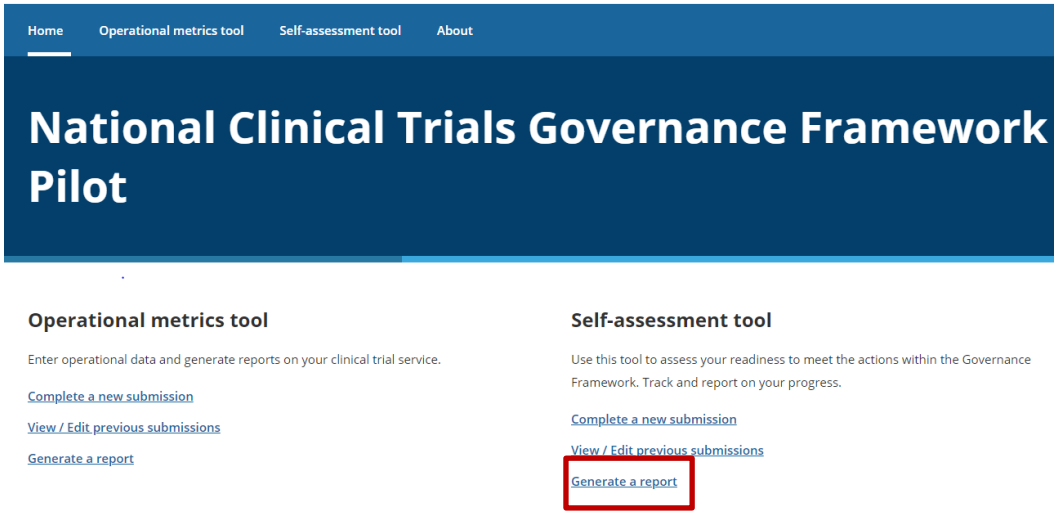
- Met (100%)
- Mostly met with some exceptions (80%)
- Partially met (50%)
- Substantially not met (20%)

	Clinical Governance	Partnering with Consumers	Total
Number of actions	18	9	27
# actions met	0	0	0
# actions not met	18	9	27
# actions mostly met	1	0	1
# actions partially met	0	0	0
# actions substantially not met	0	0	0
% of actions met	0	0	0%
% of actions not met	100%	100%	100%
% of actions mostly met	6%	0	4%
% of actions partially met	0	0	0%
% of actions substantially not met	0	0	0%

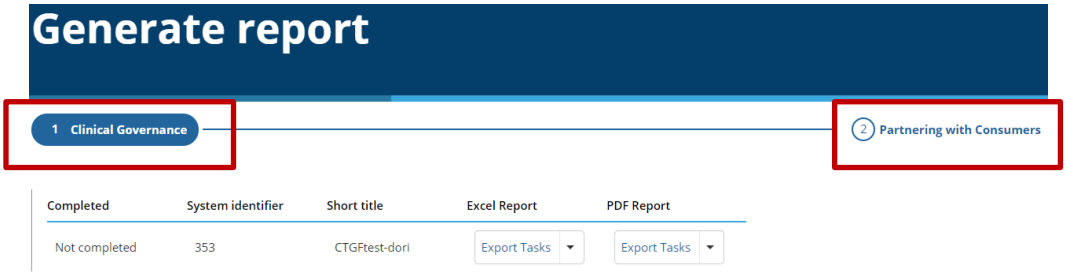
Summary reports

Following completion of the self-assessment tool, you will be able to generate summary reports on the evidence you have to meet actions within the Governance Framework and the summary of the action plan developed.

To generate reports, select the **Generate a report** on the homepage.



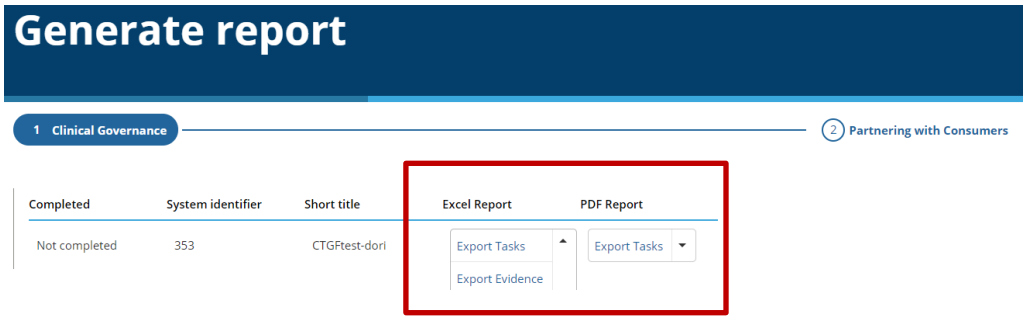
To access the reports, select the **Clinical Governance Standard** or the **Partnering with Consumers Standard** from the navigation menu.



Use the dropdown menu to select the report you wish to obtain:

- Export evidence to access the evidence summary
- Export tasks to access the action plan.

You can choose to download PDF or Excel format reports.

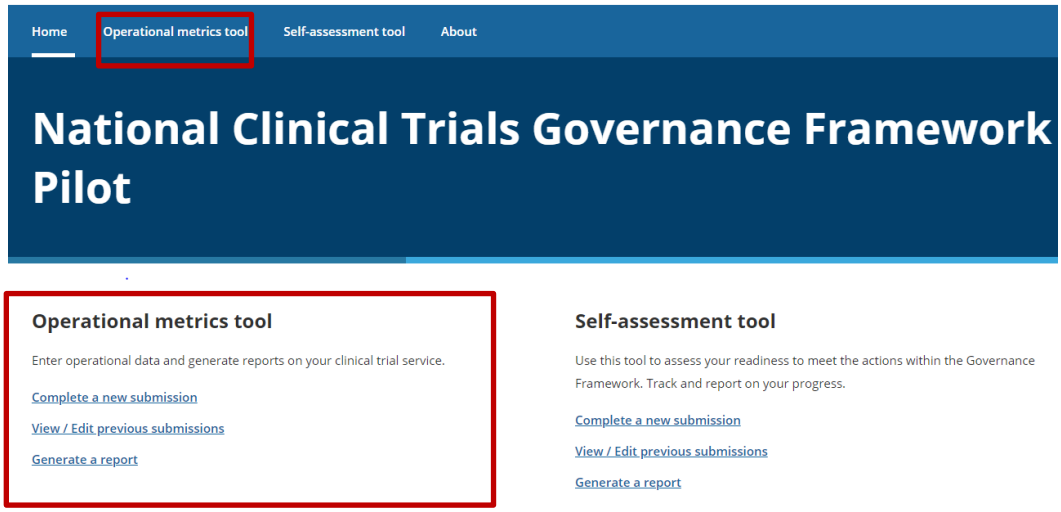


The Operational Metrics Tool

Use the operational metrics tool to enter operational data and generate reports on your clinical trial service.

Overview

The operational metrics tool is accessible directly via the homepage.



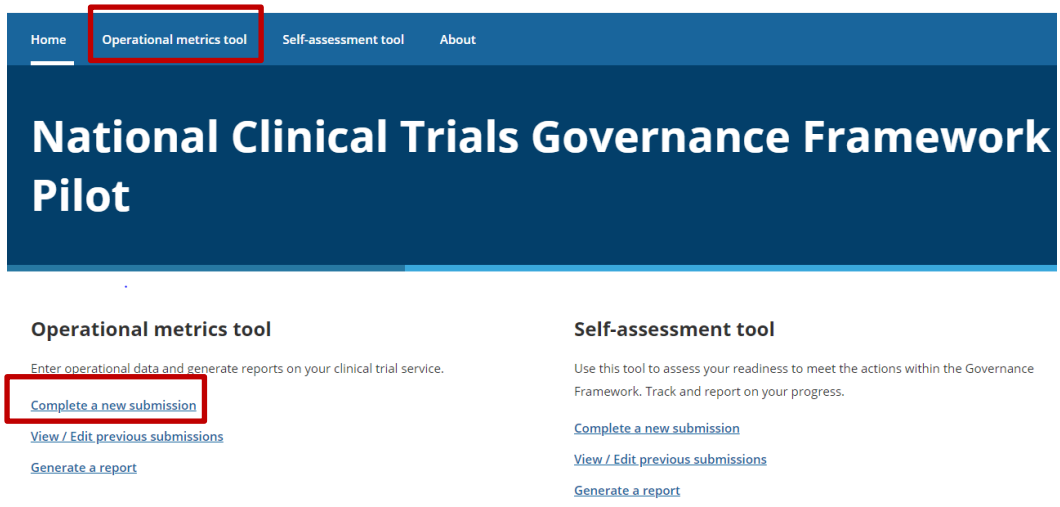
The operational metrics tool allows you to:

- Complete a new submission
- View / Edit previous submissions
- Generate reports

Completing the operational metrics tool

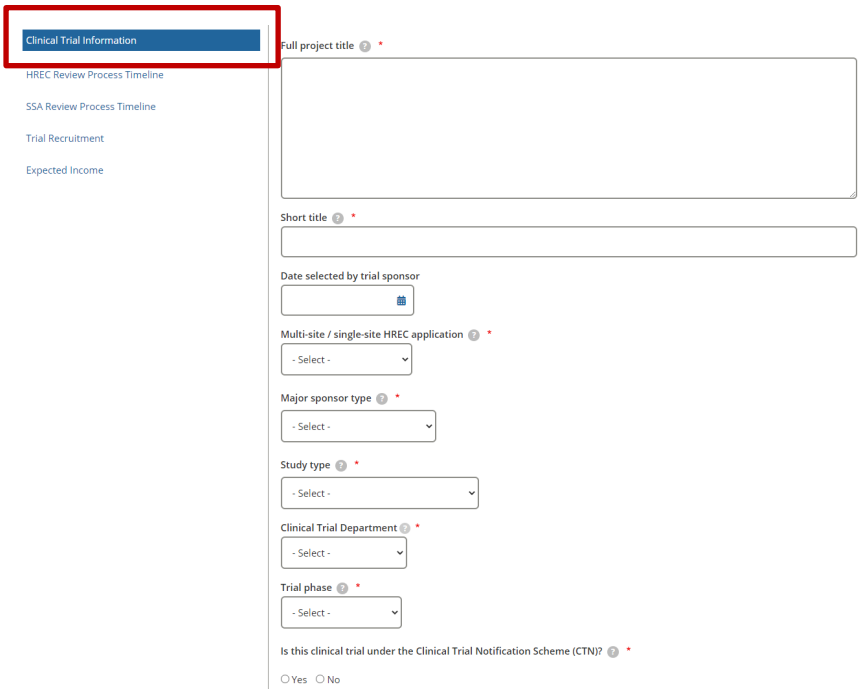
Completing a new submission

To complete a new submission, you can select **Complete a new submission** on the homepage or select **Operational metrics tool** in the upper navigation menu.

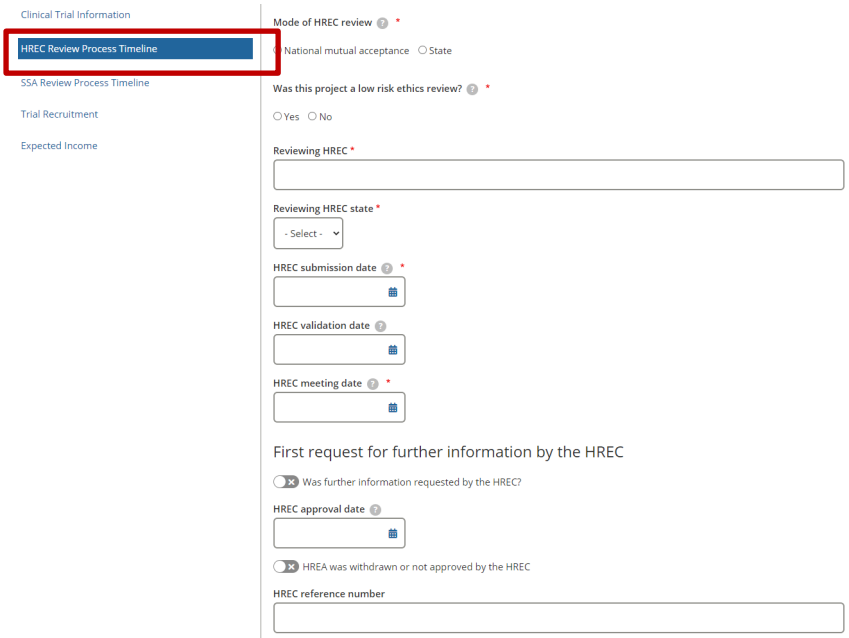


Sections of the operational metrics tool

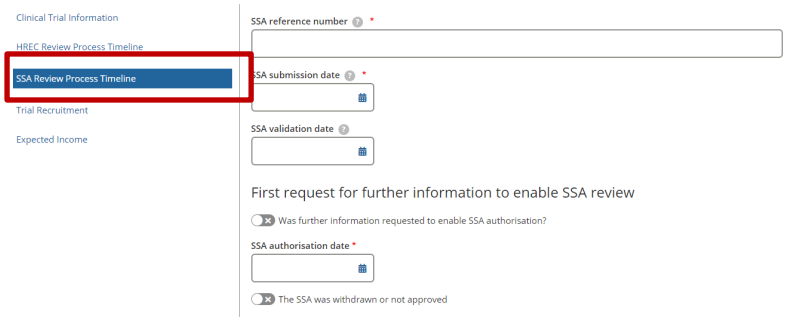
- **Clinical trial information:** you will enter information relating to the type of study, the phase and sponsor for this clinical trial. You can link the clinical trial to a specific clinical department within your health service organisation



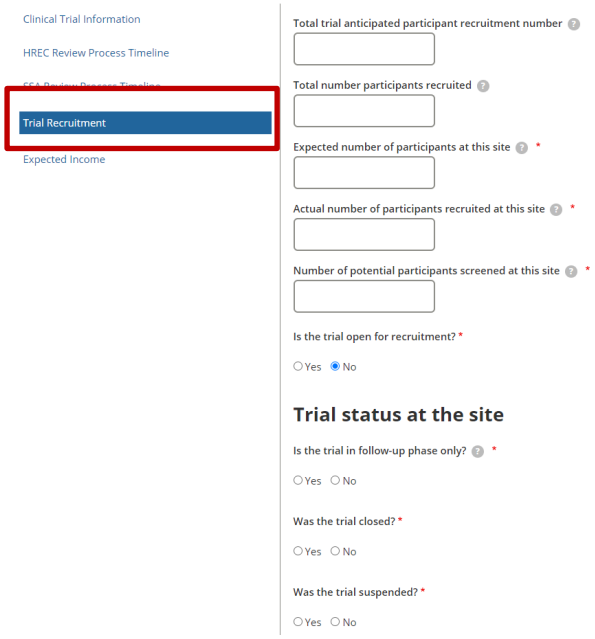
- **HREC review process timeline:** this section will help measure ethics approval times and takes into account further requests from the HREC for information. You can include up to three requests for further information



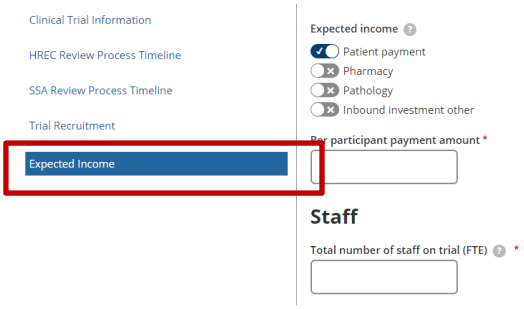
- **SSA review process and timeline:** this section will help measure the time taken to receive site authorisation and takes into account further requests for information by the health service organisation. You can include the dates of additional requests for further information and the dates your responses were provided to the health service organisation. You are able to provide the dates relating to three requests



- **Trial recruitment**: this section collects information relating to the expected recruitment target and can be used to inform the effectiveness of the site's feasibility, capacity planning and recruitment processes



- **Investment data:** the information collected in this section may be used by health service organisations to review income generated by the trial with other business and financial reports to assist with strategic planning.
  This section will also ask for an estimate of FTE involved in the trial including coordinators, investigators, pharmacists, clinical and non-clinical staff. To calculate FTE dive the number of hours worked out of the total possible hours. For example, if employed to work 24hrs out of a 38hr week, then the calculation is 24/38 = 0.6 FTE. The proportion of hours worked on a trial can be calculated in the same way.

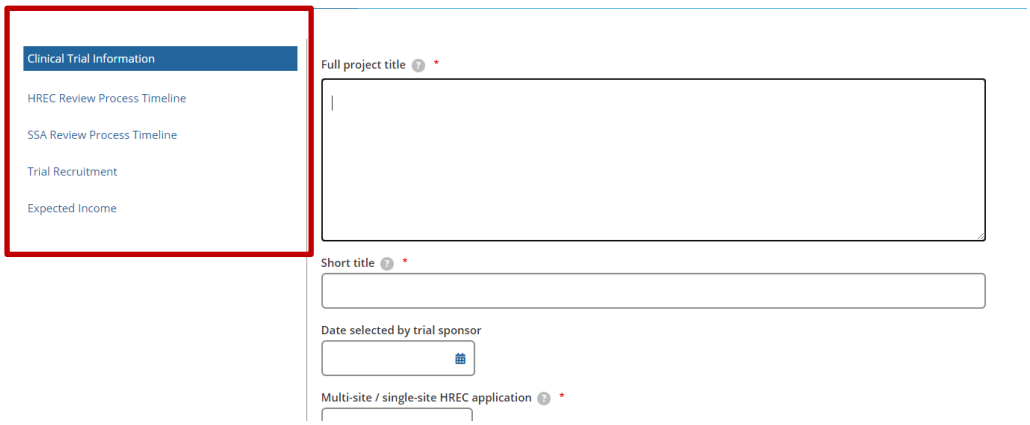


Navigating the operational metrics tool

You do not have to complete the operational metrics progressively.

You can move between sections in no particular order, enter information and select **Save and complete later.** However, you cannot **submit** the entire form until all mandatory fields are completed. Mandatory fields are indicated by a red asterisk (*).

You can access and complete each section by selecting them through the side navigation menu.

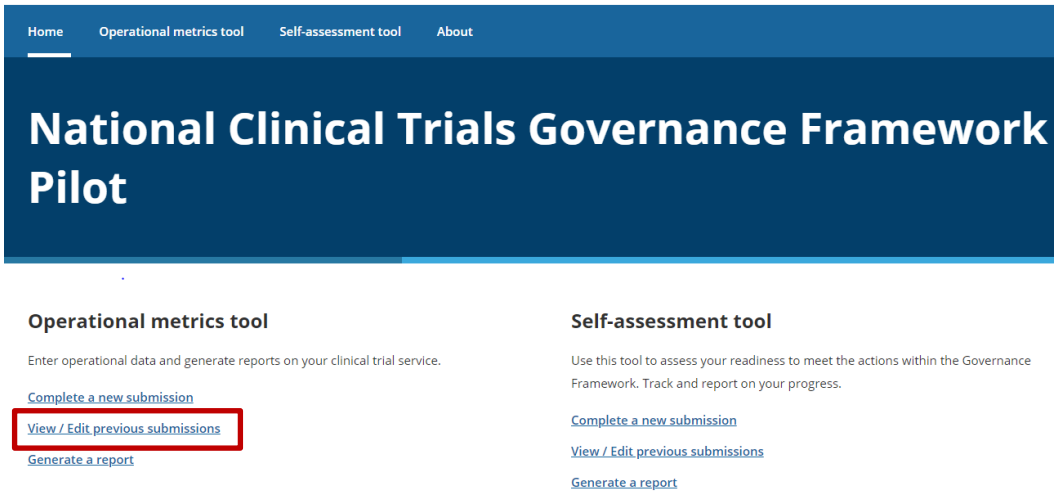


You can choose to complete the self-assessment progressively by selecting the **Previous** and **Next** at the end of each action's page.

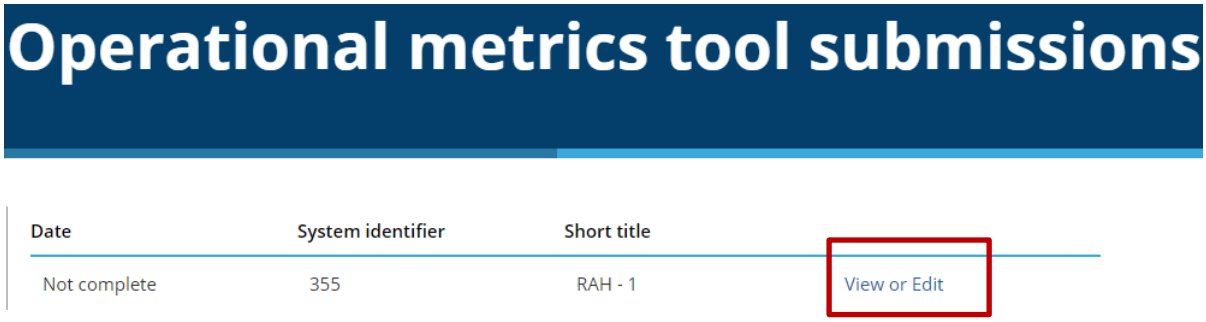
Saving and accessing drafts or previously submitted submissions

Your work is automatically saved every two minutes. You can choose to save a draft and complete it at a later date and time by selecting **Save & complete later.**

To access draft and finalised submissions, select **View/Edit previous submissions** on the homepage.



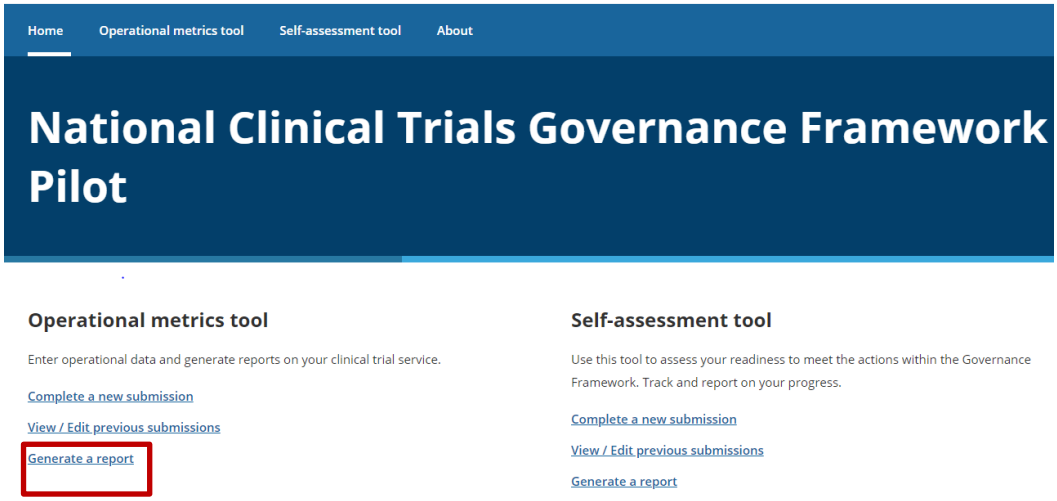
You will be able to view the list of all previous submissions. Use the short title to identify the submission you wish to access. Select **View or Edit** to access your submission.



Operational metrics reports

Generating a report

The clinical trial operational report items are calculated measures to assist trial sites and hospitals in reviewing their clinical trial activity. The report items are aligned with the National Aggregate Statistics (NAS) which are currently reported at the jurisdictional level. To generate operational reports, select the **Generate a report** on the homepage.

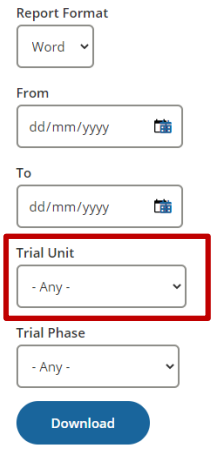


You can choose to download Word or Excel reports and choose various input parameters depending on the level of access you have been granted. For more details, see **Access to reports** section (page 38).

Within a health service organisation, you can generate reports using the following parameters:

- Date
- Trial Unit
- Trial phase

Select the trial unit/ clinical department for which you wish to obtain a report. Leave the field blank if you do not wish to filter the information and want to obtain a general report.

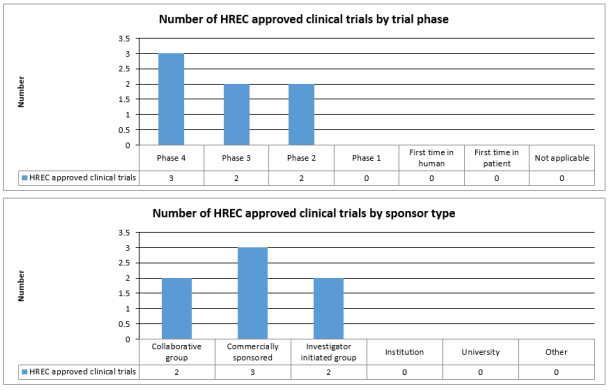


Reported metrics

There are 15 reported items, several of which are aligned to the National Aggregate Statistics (NAS).

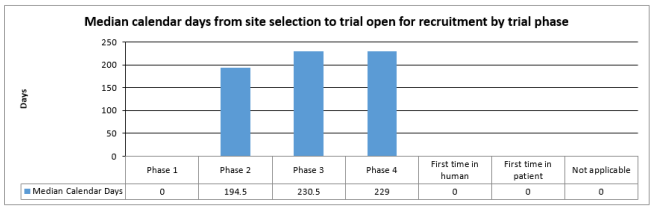
1. Total number of HREC approved clinical trials

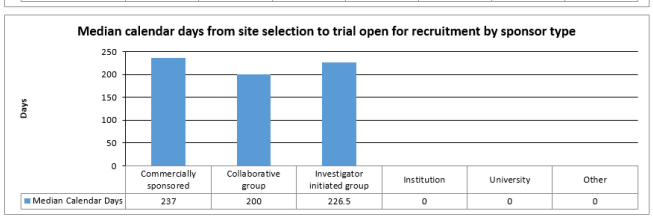
- By trial phase
- By sponsor type



2. Total and median calendar days from site selection to trial open for recruitment

- By trial phase
- By sponsor type



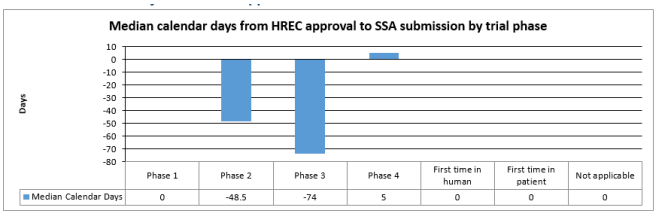


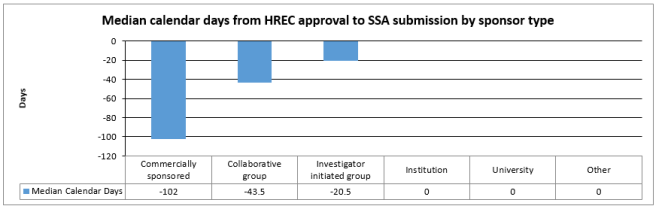
3. Total number of calendar days from HREC approval to SSA submission

HREC Reference	Trial Short Name	Sponsor Type	Trial Phase	Total number of days
HRECRAH1	RAH - 1	Collaborative group	Phase 4	-92
HRECRAH2	RAH - 2	Commercially sponsored	Phase 3	-102
HRECRAH3	RAH - 3	Collaborative group	Phase 2	5
HRECRAH4	RAH - 4	Investigator initiated group	Phase 3	-46
HRECRAH5	RAH - 5	Commercially sponsored	Phase 4	5
HRECFMC1	FMC- 1	Commercially sponsored	Phase 2	-102
HRECCH1	CH - 1	Investigator initiated group	Phase 4	5

4. Median calendar days from HREC approval to SSA submission

- By trial phase
- By sponsor type



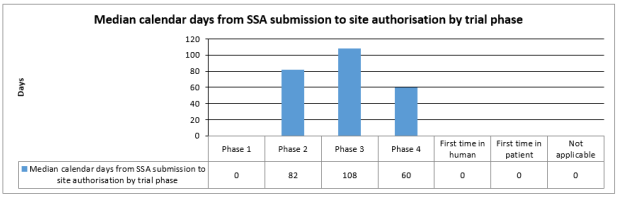


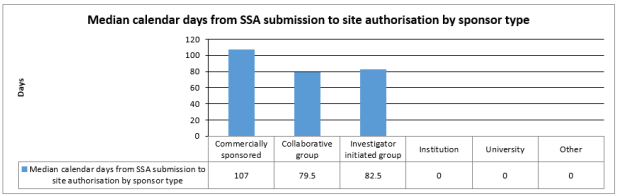
5. Total number of calendar days from SSA submission to site authorisation

HREC Reference	SSA Reference	Trial Short Name	Sponsor Type	Trial Phase	Total number of days
HRECRAH1	SSA1RAH	RAH - 1	Collaborative group	Phase 4	102
HRECRAH2	SSA2RAH	RAH - 2	Commercially sponsored	Phase 3	108
HRECRAH3	SSA3RAH	RAH - 3	Collaborative group	Phase 2	57
HRECRAH4	SSA4RAH	RAH - 4	Investigator initiated group	Phase 3	108
HRECRAH5	SSA5rah	RAH - 5	Commercially sponsored	Phase 4	60
HRECFMC1	SSA1FMC	FMC- 1	Commercially sponsored	Phase 2	107
HRECCH1	SSA1CH	CH - 1	Investigator initiated group	Phase 4	57

6. Median number of calendar days from SSA submission to site authorisation

- By trial phase
- By sponsor type





7. **HREC time to decision** (calendar days)

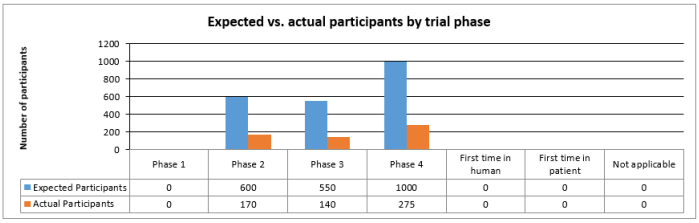
HREC Reference	Trial Short Name	Sponsor Type	Trial Phase	Days from HREA submission to first request for more information	Days from receipt of information to second request for information	Days from receipt of information to third request for information	Days from receipt of information to HREC approval	Days from HREA submission to HREC approval
HRECRAH1	RAH - 1	Collaborative group	Phase 4	21	38	0	11	70
HRECRAH2	RAH - 2	Commercially sponsored	Phase 3	32	51	0	10	93
HRECRAH3	RAH - 3	Collaborative group	Phase 2	14	23	16	11	64
HRECRAH4	RAH - 4	Investigator initiated group	Phase 3	31	17	0	25	73
HRECRAH5	RAH - 5	Commercially sponsored	Phase 4	15	23	16	11	65
HRECFMC1	FMC- 1	Commercially sponsored	Phase 2	31	17	0	25	73
HRECCH1	CH - 1	Investigator initiated group	Phase 4	25	15	0	10	50

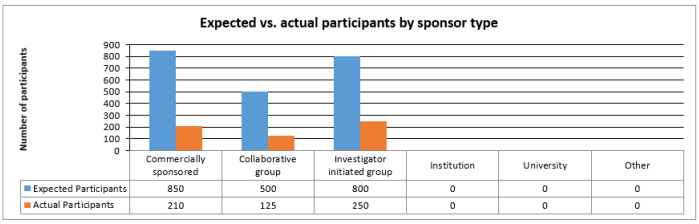
8. **Time to site authorisation** (calendar days)

HREC Reference	SSA Reference	Trial Short Name	Sponsor Type	Trial Phase	Days from SSA submission to first request for information	Days from receipt of information to second request for information	Days from receipt of information to third request for information	Days from receipt of information to HREC approval	Days from SSA submission to site authorisation
HRECRAH1	SSA1RAH	RAH - 1	Collaborative group	Phase 4	25	15	0	24	64
HRECRAH2	SSA2RAH	RAH - 2	Commercially sponsored	Phase 3	26	0	0	62	88
HRECRAH3	SSA3RAH	RAH - 3	Collaborative group	Phase 2	10	0	0	27	37
HRECRAH4	SSA4RAH	RAH - 4	Investigator initiated group	Phase 3	26	0	0	62	88
HRECRAH5	SSA5rah	RAH - 5	Commercially sponsored	Phase 4	10	0	0	30	40
HRECFMC1	SSA1FMC	FMC- 1	Commercially sponsored	Phase 2	21	0	0	61	82
HRECCH1	SSA1CH	CH - 1	Investigator initiated group	Phase 4	11	27	0	5	43

9. **Actual and expected number of participants recruited to a clinical trial**

- By trial phase
- By sponsor type

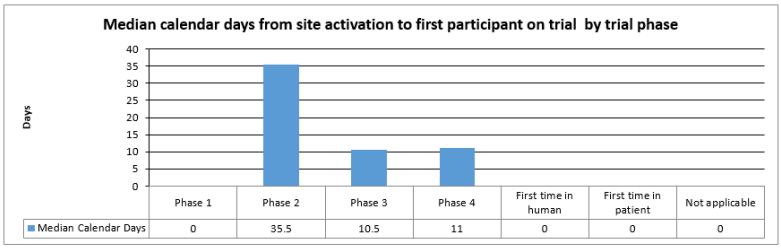


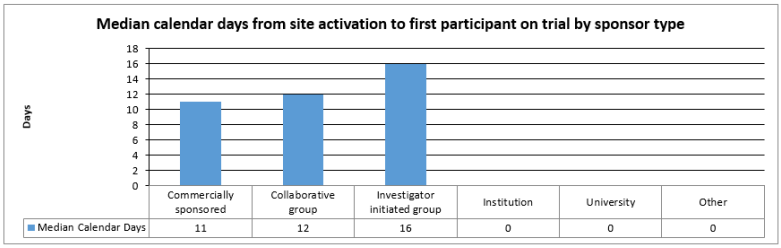


10. Total calendar days from site activation to first patient on trial

HREC Reference	SSA Reference	Trial Short Name	Sponsor Type	Trial Phase	Total Number of Days
HRECRAH1	SSA1RAH	RAH - 1	Collaborative group	Phase 4	9
HRECRAH2	SSA2RAH	RAH - 2	Commercially sponsored	Phase 3	10
HRECRAH3	SSA3RAH	RAH - 3	Collaborative group	Phase 2	15
HRECRAH4	SSA4RAH	RAH - 4	Investigator initiated group	Phase 3	11
HRECRAH5	SSA5rah	RAH - 5	Commercially sponsored	Phase 4	11
HRECFMC1	SSA1FMC	FMC- 1	Commercially sponsored	Phase 2	56
HRECCH1	SSA1CH	CH - 1	Investigator initiated group	Phase 4	21

11. Median calendar days from site activation to first patient on trial





12. **Total inbound expected investment**

- Pharmacy
- Pathology
- Recruitment
- Other income received for conducting the trial

HREC Reference	SSA Reference	Trial Short Name	Participant recruitment	Pharmacy	Pathology	Other	Total
HRECRAH1	SSA1RAH	RAH - 1	75000	20000	25000	10000	130000
HRECRAH2	SSA2RAH	RAH - 2	250000	50000	0	0	300000
HRECRAH3	SSA3RAH	RAH - 3	150000000	70000	0	0	150070000
HRECRAH4	SSA4RAH	RAH - 4	225000	70000	50000	0	345000
HRECRAH5	SSA5rah	RAH - 5	250000	42000	45000	0	337000
HRECFMC1	SSA1FMC	FMC- 1	225000	70000	50000	0	345000
HRECCH1	SSA1CH	CH - 1	100000	0	80000	50000	230000

13. Total actual in-bound investment for participant recruitment only

HREC Reference	SSA Reference	Trial Short Name	Participant recruitment	Total ($)
HRECRAH1	SSA1RAH	RAH - 1	55	8250
HRECRAH2	SSA2RAH	RAH - 2	40	10000
HRECRAH3	SSA3RAH	RAH - 3	70	10500000
HRECRAH4	SSA4RAH	RAH - 4	100	15000
HRECRAH5	SSA5rah	RAH - 5	70	17500
HRECFMC1	SSA1FMC	FMC- 1	100	15000
HRECCH1	SSA1CH	CH - 1	150	30000
			Total	10595750

14. Ratio of screened and recruited patients to FTE clinical trial staff

HREC Reference	SSA Reference	Trial Short Name	Sponsor Type	Trial Phase	Ratio of enrolled participants to FTE clinical trial staff	Ratio of screened patients to FTE clinical trial staff
HRECRAH1	SSA1RAH	RAH - 1	Collaborative group	Phase 4	55:1	106:1
HRECRAH2	SSA2RAH	RAH - 2	Commercially sponsored	Phase 3	40:2	150:2
HRECRAH3	SSA3RAH	RAH - 3	Collaborative group	Phase 2	70:2	180:2
HRECRAH4	SSA4RAH	RAH - 4	Investigator initiated group	Phase 3	100:2	250:2
HRECRAH5	SSA5rah	RAH - 5	Commercially sponsored	Phase 4	70:2	180:2
HRECFMC1	SSA1FMC	FMC- 1	Commercially sponsored	Phase 2	100:3	250:3
HRECCH1	SSA1CH	CH - 1	Investigator initiated group	Phase 4	150:3	356:3
				Ratio for All Trials	585:15	1472:15

15. Summary of clinical trial activity

HREC Reference	SSA Reference	Trial Short Name	Sponsor Type	Trial Phase	Open for recruitment	Suspended	Abandoned	Closed
HRECRAH1	SSA1RAH	RAH - 1	Collaborative group	Phase 4	Yes	No	No	No
HRECRAH2	SSA2RAH	RAH - 2	Commercially sponsored	Phase 3	Yes	No	No	No
HRECRAH3	SSA3RAH	RAH - 3	Collaborative group	Phase 2	Yes	No	No	No
HRECRAH4	SSA4RAH	RAH - 4	Investigator initiated group	Phase 3	Yes	No	No	No
HRECRAH5	SSA5rah	RAH - 5	Commercially sponsored	Phase 4	Yes	No	No	No
HRECFMC1	SSA1FMC	FMC- 1	Commercially sponsored	Phase 2	Yes	No	No	No
HRECCH1	SSA1CH	CH - 1	Investigator initiated group	Phase 4	Yes	No	No	No

Access to reports

Users can generate various reports according to their level of access:

Basic access	Trial unit/ clinical department access	Health service organisation access	National access
Users are only able to access their own submissions and generate basic reports.	Users are able to access submissions from other users within the same trial units/ clinical departments and generate reports for their trial units/ clinical departments	Users are able to access submissions from all users within the same health service organisation and generate reports for specific trial units/ clinical departments or for the whole health service organisation.	Users are able to access all submissions from all users and generate reports for specific trial units/ clinical departments, specific health service organisations, specific jurisdictions and national reports. This access has only been granted to the Commission.

Contact us

If you have any questions about the Clinical Trials portal or encounter any issues, please contact the Commission's Clinical Trials team at: HMR@safetyandquality.gov.au.